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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,442	01/20/2000	James E. Darnell JR.	600-1-195B	4454

7590 04/15/2003  
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/488,442

Applicant(s)

DARNELL ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires three months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1,97,108-113 and 115-119.Claim(s) withdrawn from consideration: 98-107.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0403.
10. ☒ Other: See Continuation Sheet

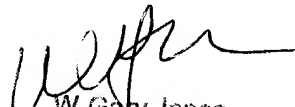
Continuation of 5. does NOT place the application in condition for allowance because: As discussed below, the IDS has not been considered, as it is not proper since there is no statement accompanying the IDS. Therefore, to the extent that the arguments are directed to references cited on the IDS, the arguments are moot.

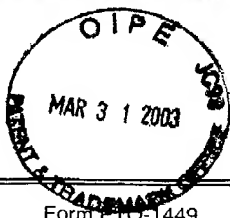
With regard to the 101, the response asserts that the amino acid sequences of Stat3 may be used to generate antibodies. This is not a specific or substantial utility, because once antibodies are generated, it is unclear what they will be specific and substantially used for. The response asserts that the Stat3 is involved in intracellular signaling pathways, however it is unclear how this information will be used in a specific or substantial way. The response also relies upon several post filing date articles to demonstrate utility, however, as previously noted, the specification does not discuss these utilities, therefore, at the time the invention was made, the instant invention did not have a specific or substantial utility. The instant claims receive priority to March 11, 1994, therefore at the time of the effective filing date, no specific, substantial or well-established utility existed. None of the references discussed in the response are available prior to 1994. In the event that applicant traverses the effective filing date of March 11, 1994 and believes that the filing date of the claims should be January 20, 2000, applicant's own art, namely Genbank Accession Number AAA19452 and PNAS, Vol. 91, No. 11, pages 4806-4810, 1994 is art against the claims. The claims do not receive one priority date for determination of art related rejections and another priority date for utility related rejections.

With regard to the 112/1st Enablement rejection, the response asserts that a stat3 fragment or mutant would be capable of competing with the full length functional protein for binding to components of the signaling pathway and could be used to decrease an activity initiated by the stimulus bound to the receptor. This argument has been thoroughly reviewed, but is not found persuasive because the specification fails to teach how this decrease in activity initiated by the stimulus bound to a receptor may be used. The skilled artisan would be unable to use the invention without determine how these activities and effects affect the pathway. Moreover, the response relies upon art filed after the effective filing date of 1994 to support their position. This does not provide enablement for the invention at the time the invention was made, i.e. 1994. Additionally, the response provides extensive reasonings why an immunogenic fragment would be understood and the skilled artisan would be able to identify immunogenic fragments. This argument has been thoroughly reviewed, but is not found persuasive because it is unpredictable which fragments would contain immunogenic activity. While further experimentation could be performed, it is unpredictable which fragments would have activity.

With regard to the Description rejection, the question of description relies upon what has been described and not what could be identified. The specification teaches a single asserted immunogenic fragment. This is not representative of the genus of immunogenic fragments.

Continuation of 10. Other: The information disclosure statement filed March 31, 2003 is not proper. The response asserts that the IDS is filed prior to a final action, however, the application is after final. The MPEP provides in 37 CFR 1.97 that, " provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by: (1) The statement specified in paragraph (e) of this section; and (2) The fee set forth in § 1.17(p). (e) A statement under this section must state either: (1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or (2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. In the instant case, the response has not provided a statement therefore the IDS has not been considered..

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600



Sheet 1 of 1

Form PTO-1449 IRSY. 7.801 U.S. Department of Commerce Patent and Trademark Office  LIST OF DOCUMENTARY INFORMATION CITED BY APPLICANT (Use several sheets if necessary)	ATTORNEY DOCKET NO.	600-1-195B
	SERIAL NO.	09/488,442
	APPLICANT	James E. Darnell, Jr. et al.
	FILING DATE	January 20, 2000
	GROUP	1634

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BW	Dalton et al., Semin Oncol, 26:23-7 (1999), Abstract
	BX	Darnell, Jr. et al., Science, 277:1630-1635 (1997)
	BY	Kodama et al., Circulation Research, 81:656-663 (1997)
	BZ	Kunisada et al., Circulation, 346-352 (1998)
	CA	Niu et al., Cancer Research, 59:5059-5063 (1999)
	CB	Rani et al., The Journal of Biological Chemistry, 274:32507-32511 (1999)
	CC	Takeda et al., Proc. Natl. Acad. Sci., 94:3801-3804 (1997)
	CD	Turkson et al., Molecular and Cellular Biology, 18:2545-2552 (1998)
	CE	Turkson et al., Molecular and Cellular Biology, 19:7519-7528 (1999)
	CF	Zhong et al., Science, 264:95-98 (1994)

EXAMINER:	DATE CONSIDERED:
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	